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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,513	01/15/2004	Marc Lemaire	Serie 6093	5797

7590 03/05/2007

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,513	LEMAIRE, MARC	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Claims 42-62 are pending.

The Examiner acknowledges Applicant's remarks filed on 8/18/06. It is regretted that another non-final action must be sent. Upon review of the Office Action, Applicant is invited to contact the Examiner to arrange a telephone interview to expedite prosecution of the case.

Comment: Please put a period at the end of claim 62.

Withdrawn rejections:

Claims 64 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Cancellation of these claims renders the rejection moot.

Claims 63-66 were rejected under 35 U.S.C. 102(b) as being anticipated by Mondain-Monval (US 4,820,258). Cancellation of these claims renders the rejection moot.

Claims 63-66 were rejected under 35 U.S.C. 102(a) as being anticipated by Homi et al. (Anesthesiology 2003, 99, 876-881). Cancellation of these claims renders the rejection moot.

Claims 42-62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Homi et al. (Anesthesiology 2003, 99, 876-881) in view of Mondain-Monval (US 4,820,258). Applicant has perfected the priority document to overcome the Homi et al. reference. The Examiner withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or minimizing post-ischemic brain cell deterioration in humans comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide and xenon, does not reasonably provide enablement for a method with any and all nitrous oxide donors and xenon donors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that a method of treating or minimizing post-ischemic brain cell deterioration in humans comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less (Instant specification page 9, lines 1-6). However, Applicant is purporting to use all nitrous oxide donors and xenon donors.

2) Nature of the invention

The nature of the invention is directed to a method of treating or minimizing post-ischemic brain cell deterioration in humans comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

5) Level or degree of predictability, or a lack thereof, in the art

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a method of treating or minimizing post-ischemic brain cell deterioration in humans comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less, it remains silent on any and all nitrous oxide donors and xenon donors.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method with any and all nitrous oxide donors and xenon donors for treating post-ischemic brain cell deterioration.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to test each every chemical entity that might possibly be a nitrous oxide donor or xenon donor in the instant method. This is especially difficult because there is no guidance as to the chemical structure of these donors except that nitrous oxide or xenon must be provided. This would then further require experimentation on animal models before clinical trials could be initiated. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the method of the instant application does in fact work with any and all nitrous oxide and xenon donors.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating or minimizing post-ischemic brain cell deterioration or providing a neuroprotective action in the brain of a human comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less, does not reasonably provide enablement for a method with any and all concentrations of nitrous oxide and xenon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are

weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that a method of treating or minimizing post-ischemic brain cell deterioration or providing a neuroprotective action in the brain of a human comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less (Instant specification page 9, lines 1-6). However, Applicant is purporting to use all concentrations of nitrous oxide and xenon.

2) Nature of the invention

The nature of the invention is directed to a method of treating or minimizing post-ischemic brain cell deterioration or providing a neuroprotective action in the brain of a human comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal composition comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators conducting scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

5) Level or degree of predictability, or a lack thereof, in the art

Applicant discloses that there is a neurotoxic effect, which is variable according to the dose administered of nitrous oxide and xenon (specification page 8, lines 29-33).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a method of treating or minimizing post-ischemic brain cell deterioration or providing a neuroprotective action in the brain of a human comprising administering by inhalation to a human a therapeutically-effective amount of a medicinal comprising nitrous oxide at a dose of 75% by volume or less and xenon at a dose of 50% by volume or less, it remains silent on any and all concentrations of nitrous oxide and xenon and specifically warns of a neurotoxic effect depending on the dosage administered.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method with any and all concentrations of nitrous oxide and xenon for treating post-ischemic brain cell deterioration or providing a neuroprotective effect.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to test each permutation of nitrous oxide, xenon and additional gases in expensive animal models to see if the claimed method worked. As

a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the method of the instant application does in fact work with any and all concentrations of nitrous oxide and xenon.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 42, 43, 46, 49, 50, and 51 recite the limitation "nitrous oxide donor" and "xenon donor". It is unclear to the Examiner the chemical formula of such donors and the specification does not provide any guidance thus making the claim indefinite. Claims 44, 45, 47, 48, and 52-54 are rejected as being indefinite because they are dependent on an indefinite base claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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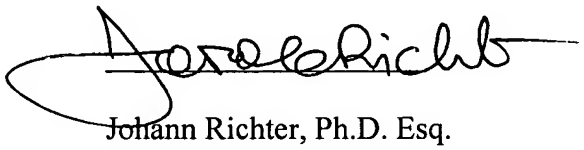

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